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January 25, 2006

The Honorable Kent A. Jordan
J. Caleb Boggs Federal Building
844 N. King Street
Room 6325
Lockbox 10
Wilmington, DE 19801

Re: Discovery Dispute in *Biovail v. Andrx Pharmaceuticals LLC et al.*, Civil Action No. 1:05-cv-0586

To his Honor, Judge Jordan,

Andrx Pharmaceuticals, LLC and Andrx Corporation (collectively "Andrx") respectfully request that the Court compel plaintiff Biovail Laboratories International SRL (herein "Biovail") to provide answers to Andrx's Interrogatories 1 – 4 and 6 – 9, and to produce documents called for in Andrx's Document Request Nos. 1 – 34, 36 – 48, and 50 – 62. (See Exhibit A and Exhibit B respectively). A copy of this letter was delivered to Biovail's counsel by 8:30 am today.

I. Biovail's Answers To Interrogatories 1 – 4 And 6 – 9 Are Insufficient.

In Interrogatory Nos. 7, 2, 3 and 6, Andrx sought information that is indisputably relevant to the validity or invalidity of the patent-in-suit. Andrx has alleged that U.S. Patent No. 5,529,791 (the "'791 patent") is invalid, (D.I. No. 7), and Biovail has not challenged the legal sufficiency of those allegations under Federal Rule of Civil Procedure 12(b), (c) or (e). Accordingly, validity is in the case. Biovail nevertheless has refused to provide the requested information, and claims it has no obligation to do so until Andrx offers additional contentions satisfactory to Biovail regarding invalidity. In short, Biovail has proclaimed itself the judge of what issues are and are not sufficiently pleaded. The remainder of Biovail's objections primarily are unsubstantiated claims of burdensomeness, which are plainly insufficient.

To the extent that Biovail has provided any answers to the interrogatories, these answers are incomplete. For instance, instead of providing the requested dates of conception and reduction to practice for Interrogatory No. 2, Biovail answered only that the dates are some unspecified time at or before the filing of the application, and referred Andrx to the inventors. This incomplete answer is prejudicial to Andrx because the actual facts may provide a critical date with respect to prior art and validity under Section 102 of the Patent Act.

Andrx's Interrogatory No. 8 seeks information directly related to claim construction in so far as it asks when, in Biovail's manufacturing process, does Biovail believe its products first

embody claims in the '791 patent. Biovail's answer directs Andrx to the Chemistry, Manufacturing and Controls ("CMC") portion of Biovail's New Drug Application ("NDA") and identifies individuals knowledgeable about Biovail's manufacturing processes. That response is inadequate because it points to a stack of documents and two people, instead of the actual answers – which Biovail apparently knows.

Interrogatory No. 9 asks Biovail to identify each person who provided information that was included in, or considered for inclusion in these interrogatories or Andrx's request for the production of documents and things, and whether the files for each person were searched for information and responsive documents. Andrx is entitled to learn the identities of these people, and to seek their depositions. Biovail's privilege objections are frivolous.

Andrx's Interrogatory No. 1 asks Biovail to state the legal and factual bases for its allegations that Andrx's product has infringed or will infringe one of more claims of the patent-in-suit. After stonewalling until the discovery conference became certain, Biovail amended its non-answer to Interrogatory No. 1, with a longer, yet still incomplete answer. (See Exhibit C.) At bottom, Andrx is asking why and under what theory it has been hauled into Court, thereby automatically preventing the FDA from approving Andrx's would-be competitive drug for 30 months. Before suing, Biovail presumably formulated a claim construction under which Andrx infringes. Andrx is entitled to know why Biovail thinks Andrx infringes.

Similarly, interrogatory No. 4 asks Biovail to describe any facts upon which Biovail may rely to justify differences in claim construction between this case and its earlier case against Andrx in which the district court and the Federal Circuit construed several terms of the '791 patent claims. If Biovail will contend that it is not bound by those courts' prior constructions, Andrx is entitled to know why and upon what facts Biovail will rely for its different construction.

II. Biovail's Responses to Andrx's Document Requests are Incomplete.

Biovail also has failed to produce documents and things responsive to many of Andrx's requests for production. Because of the number of document requests at issue (1 – 34, 36 – 48, and 50 – 62), Andrx has made an effort to group them into categories A through G.[1]

> **Category A:** Documents and things related to proceedings or conflicts involving subject matter disclosed or claimed in the patent-in-suit (or related foreign patents and applications) including documents re: facts underlying the pleadings in this case: (1) (incomplete), (2) (incomplete), (3) (incomplete), (4) (incomplete), (5) (incomplete), (8) (incomplete), (39) (incomplete), (40), (41) (incomplete), (50) (incomplete), (56), (57), (60) (incomplete), (61) (incomplete), (62) (incomplete);
>
> **Category B:** Documents and things relating to the acts of alleged invention (not including secondary considerations) – dates of invention etc….: (6)

[1] A parenthetical note that a response is "incomplete" means that, though a small amount of material may have been produced, it would be surprising if more were not available and readily accessible.

(incomplete), (7) (incomplete), (9) (incomplete), (10), (18) (incomplete), (42), (43), (44), (51) (incomplete), (52) (incomplete), (54) (incomplete);

Category C: Documents related to the testing, R&D, formulations of products that Biovail asserts are covered by the patent: (11) (incomplete), (12) (incomplete), (13) (incomplete);

Category D: Documents and things relating to secondary considerations of non-obviousness: (14) (incomplete), (15) (incomplete), (16) (incomplete), (17) (incomplete), (20), (21), (22), (23), (31), (34), (47) (incomplete), (48) (incomplete), (55) (incomplete);

Category E: Regulatory approval documents here and abroad. (19) (incomplete), (46) (incomplete);

Category F: Documents related to the patent-in-suit or subject matter in the patent-in-suit: (24) (incomplete), (25) (incomplete), (27) (incomplete), (28) (incomplete), (30) (incomplete), (32) (incomplete), (33) (incomplete), (36) (incomplete), (37), (38); and

Category G: Documents related to third parties: (26) (incomplete), (29) (incomplete), (45) (incomplete), (53) (incomplete), (59) (incomplete).

Again, Biovail has refused to produce any documents directed to invalidity issues (e.g., non-NDA marketing and advertising material, information related to secondary considerations and documents and things related to the "invention" in the '791 patent). Further, in many instances, Biovail has based its refusal to produce relevant materials on the grounds that it produced that material in a prior litigation. Biovail is aware, however that Andrx no longer has those documents from the older case. Further, before the New Year, Biovail agreed to deliver those documents on an expedited basis, yet Andrx is still awaiting that production.

In sum, Andrx's discovery requests are plainly relevant to the issues in the pleadings. Biovail is not entitled to re-define relevance by simply declaring the pleadings insufficient. Nor is Biovail entitled to withhold the bases for its allegations.

Respectfully submitted,

Matthew C. Marlowe